

### **REMARKS**

In a May 2, 2006 Preliminary Amendment, new Claims 34-50 were added. Claims 1-23 and 33 were subsequently cancelled. Claims 37, 39 and 40 were subsequently withdrawn. In the May 29, 2007 and January 10, 2008 Amendments, Claim 51 and Claim 52 were respectively added. Presently, Claim 53 is added. Accordingly, Claims 24-32, 34-36, 38 and 41-53 are currently pending. Claims 24 and 53 are independent claims.

### **Rejection under 35 U.S.C. §103 in View of *Beckman***

Claims 24-32, 34-36, 38 and 41-50 are rejected under 35 U.S.C. §103 as being obvious over *Beckman et al.* (U.S. Patent Application No. 2002/0015697, hereinafter "*Beckman*"). (See Office Action pages 3-6.)

*Beckman* provides a method for reducing a microbial population on a surface with a composition that comprises a transition metal as the active ingredient. In particular, *Beckman* state that its compositions reduce microbial populations by causing a "transition metal overload." (See paragraph [0040] of *Beckman*.) That is, *Beckman* requires a transition metal to reduce microbial populations. Along with the transition metal, the *Beckman* composition includes a non-oxidant stress inducer such as chitosan.

The pending claims recite a method of inhibiting the intrusion of micro-organisms into a body cavity of a mammal by applying a "fully reversible" hydrogel composition. The hydrogel comprises 1) a poly(N-vinyl lactam), 2) a polysaccharide and 3) water. The hydrogel is a lubricious gelatinous composition.

The "fully reversible" hydrogel forms since the polyvinyl lactam and the polysaccharide are present in a specific ratio. The range of the ratio of the amount by weight of the poly(N-vinyl) lactam to the amount by weight of the polysaccharide is about 5 : 1 to about 75 : 1.

Claim 24 has presently been further amended to emphasize that antibiotics/antimicrobials are not necessary to be included in the compositions to reduce/eliminate micro-organisms. Support for this language is throughout the specification, including, for example, at page 5, lines 26-27; page 6, lines 8-9; and page 15, lines 8-10.

**Key Ingredient of Beckman Composition Not Included in Present Invention Composition to Achieve Same Function**

The pending independent claims (i.e., Claims 24 and 53) recite a “method of inhibiting the intrusion of micro-organisms into a body cavity of a mammal...” The claims also include the language that the hydrogel is capable of “reducing or eliminating the level of micro-organisms.” The present invention composition achieves this goal of reducing/eliminating micro-organisms using three ingredients.

*Beckman* has a goal similar to the one of the present invention. However, *Beckman* requires a transition metal for reducing microbial populations. Transition metals are known to potentially have toxic effects for eukaryotes. For example, transition metals are known to potentially enhance bacterial growth and/or dramatically worsen bacterial infections, i.e., to be pro-microbial. See paragraph [0038] of *Beckman*.

One of the objectives of the present invention is to avoid toxic side effects of compositions which are used to inhibit micro-organisms in mammalian body cavities. The specification discusses the serious drawbacks of including certain additives in such compositions. For example, on page 2, lines 24-27, of the specification, the disadvantages of adding antibiotics to teat compositions are discussed; and on page 4, lines 23-26, of the specification, the toxicological concerns of adding certain catalysts to teat compositions are discussed. Similarly, as outlined above, transition metals also have toxic effects.

The present invention composition surprisingly achieves the goal of the *Beckman* composition but without adding the potentially toxic ingredient of Beckman. Since an antimicrobial effect is achieved by the present invention composition, there is no reason to

place a potentially toxic ingredient in the composition (i.e., transition metal). “[T]he omission of an element and retention of its function is an indicia of unobviousness. *In re Edge*, 359 F.2d 896, 149 U.S.P.Q. 556 (CCPA 1966).” See M.P.E.P. §2144.04 (II)(B).

Moreover, many of the “therapeutic performance enhancing agents” recited in pending Claim 46 are not compatible with addition of a transition metal. For example, agents listed in Claim 46 include peroxides. The transition metal iron forms a highly reactive hydroxyl radical. (See paragraph [0037] of *Beckman*.)

#### New Claim 53

New Claim 53 recites the method of Claim 24 except that the composition “consists essentially of” poly(N-vinyl) lactam, polysaccharide and water (i.e., instead of “comprises”).

The addition of a transition metal, such as iron, to the composition that “consists essentially of” poly(N-vinyl) lactam, polysaccharide and water would materially affect the basic and novel characteristics of the composition. For example, as disclosed by *Beckman*, it is well known in the art that transition metals, such as iron, can be “pro-microbial” and toxic. (See paragraphs [0036] to [0038].) Thus, the composition of the present invention *without* a transition metal is safer for the mammalian recipient and provides a safer environmental profile.

It is *always* a principal goal that toxic effects of compositions used on mammals be minimized. The inclusion of transition metals with such compositions would lead to a higher risk of toxic effects than when composition is used without such metals. Moreover, as discussed above, in the specification, it is shown that a minimization of toxic effects was *specifically* contemplated by the invention. Accordingly, excluding an agent which is known to have potentially toxic effects, such as transition metals, was contemplated. The “consisting essentially of” language excludes such agents.

**Beckman Does Not Disclose All Three Elements of Pending Claims in One Embodiment**

The Examiner alleges that “the gels taught by *Beckman* are also ‘fully reversible’ since every component of the present composition is disclosed by *Beckman*.” (See Office Action, page 8, penultimate paragraph.)

The three ingredients of the composition recited in the pending independent claims do not appear in one embodiment of *Beckman*. Moreover, *Beckman* teaches away from the three components being in one embodiment.

The Examiner states that *Beckman* discloses water in their composition in paragraph [0155]. (See penultimate sentence of page 4 of the Office Action.) However, the Examiner fails to consider that *Beckman* discloses several different embodiments (i.e., forms) of its compositions. One form of the *Beckman* composition is a gel. Another form of the *Beckman* composition is an oral rinse. These two different forms are incompatible with one another. That is, water does not appear in the *Beckman* gel and visa versa. A discussion of these points follows.

In paragraph [0058], embodiments of the *Beckman* composition are disclosed which allow for enhanced adhesion of the composition to surfaces. Among these embodiments are viscous gels. In particular, it is stated:

[T]he methods of the present invention can optionally employ equipment such as nebulizers, which result in foaming, or other compounds and procedures known to those skilled in the art which result in a foam or viscous gel to ensure adequate exposure of the disinfectant solutions to the treated surface. The foam or gel, by adhering to the surface of, for example, a food product, provides a longer exposure time than would be achieved with a simple liquid. (Emphasis added.)

Paragraph [0058] is the only section where gels are disclosed. Water is not disclosed as being used with the gel.

Paragraph [0155] is the only section where water is included as a component of the composition. The form of the *Beckman* composition which contains water is an oral rinse. In particular, it is stated, “in yet another embodiment..., the composition of the present invention includes a preparation of free iron and an oral rinse.”

Thus, the gel form of the *Beckman* composition and the form of the *Beckman* composition which contains water are not in the same embodiment. In fact, the gel of *Beckman* and the oral rinse of *Beckman* have two opposing purposes. The gel is made to adhere to a surface for an extended period of time; whereas, the rinse is clearly meant to be in contact with the oral cavity for mere seconds. Water is not disclosed as being used with the *Beckman* gel.

*Beckman* also discloses “wound dressings” in paragraphs [0142] to [0147]. In paragraph [0145], *Beckman* provides a long laundry list of additional materials that could be contained in “wound dressings.” Included in that long list is polyvinylpyrrolidone. This is the only embodiment in *Beckman* where polyvinylpyrrolidone is disclosed. Wound dressings clearly cannot be in the form of an oral rinse, and thus does not contain water.

Thus, *Beckman* does not disclose all three elements of the pending claims in one embodiment. In one embodiment, *Beckman* discloses an oral rinse containing water, a transition metal and chitosan. In contrast, the composition of the present invention further contains a poly(N-vinyl lactam and in the form of a hydrogel. In another embodiment, *Beckman* discloses a viscous gel containing a transition metal and chitosan, and optionally, polyvinylpyrrolidone. In contrast, the composition of the present invention further contains water.

*Beckman* does not disclose a gel and water together. Thus, *Beckman* can not disclose a hydrogel.

In contrast to *Beckman*, the present claims recite a hydrogel. Independent Claims 24 and 53 recite that the water content of the hydrogel is about 25 wt% to 90 wt%.

The Examiner states that “[g]enerally, mere optimization of ranges will not support the patentability of subject matter encompassed by the prior art...” (See Office Action page 5, 2<sup>nd</sup> paragraph.) However, the components of the compositions of the present invention are not mere optimizations of ranges. Instead, as demonstrated above, the components of the compositions are different. The difference in the components creates different rheological behaviors of the compositions.

Accordingly, Applicants request withdrawal of this obviousness rejection.

**Rejection under 35 U.S.C. §103 *Beckman* in view of *Stoner***

Claim 51 is rejected under 35 U.S.C. §103 as being obvious over *Beckman* in view of U.S. Patent No. 4,925,033 (hereinafter “*Stoner*”). (See Office Action pages 6-8.)

Since the claim upon which Claim 51 depends is not obvious over *Beckman*, as discussed above, the further disclosure by *Stoner* does not render Claim 51 obvious. Accordingly, Applicants request withdrawal of this obviousness rejection.

Applicants do not believe that any fees are due other than those for the petition for the extension of time and the Notice of Appeal. However, if any other fees are due, please deduct such sum from Deposit Account No. 08-2461.

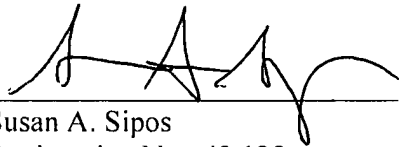
Applicant: Gruening et al.  
Serial No.: 10/788,663  
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Applicants respectfully submit that the application is in all respects complete and in condition for allowance. If the Examiner has any questions or comments, it is respectfully requested that the Examiner contact Applicants' undersigned attorney at the telephone number provided below.

Respectfully submitted,



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